PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference NO 7696/WO	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/EP2005/001265	International filing date *(day/month/year)* 08.02.2005	Priority date *(day/month/year)* 10.02.2004
International Patent Classification (IPC) or national classification and IPC C09B61/00, A23L1/275, A61K7/48, A61K31/015		
Applicant NESTEC S.A. et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09.09.2005	23.02.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Ketterer, M Telephone No. +49 89 2399-

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2005/001265

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-15 as originally filed

Claims, Numbers

1-24 as originally filed

Drawings, Sheets

1/5-5/5 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	20,21
	No:	Claims	1-19,22-24
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-24
Industrial applicability (IA)	Yes:	Claims	1-24
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

V. Reference is made to the following documents:

D1: US -A- 5 310 554
D2: US -A- 5 612 485
D3: Derwent abstract 1997-053021[06] & CN -A- 01 077 190
D4: WO -A- 96/19215
D5: EP -A- 0 832 569
D6: WO -A- 02/12183
D7: WO -A- 01/83437

V.1. The present application does not meet the requirements of Article 33(1) PCT, because the subject-matter of claims 1-24 is not novel resp. not inventive in the sense of the Articles 33(2) and 33(3) PCT.

V.1.1. The cis-isomer (9-cis) enriched compositions of D1 (see whole document) as well as the process leading to the compositions are regarded being novelty destroying for claims 1-19, 22-24. The compositions of D1 contain at least 5% 9-cis beta-carotene and <= 40% of all-trans-beta-carotene, in some cases the 9-cis beta-carotene content can be 75% or higher. They are suitable for administration to humans or other animals, particularly for oral delivery, in a variety of formulations and dosages as pharmaceutical agents or as dietary supplements.
V.1.1.1. Claims 20 and 21 are not inventive over D1, because a further enrichement by using phase separation methods with organic solvents with a final isolation step of the cis isomer is obvious from D1, also as a further treating step for the already prepared 'primary composition'.

V.1.2. D2 deals with carotenoid compositions containing cis- beta-carotene in high concentration; they are useful in food and pharmaceutical applications and are expected to have improved effect in use in medical applications, e.g. in the healing and prevention of cancer, cardiovascular disease etc. D2 (see examples,claims) is novelty destroying for claims 1-19,22-24.

V.1.3. The process disclosed in D3 leads to crystals containing 70-95 percent trans-beta-carotene and an oil containing 30-90 percent cis- beta-carotene (which represents a

composition being enriched in cis-isomer) with the purpose to be used for prevention of cancer and health care. The claimed subject matter of claims 1-24 is not novel resp. inventive vis à vis D3. Also here, as already mentioned in the context to D1, a further isolation resp. enrichement step to increase the cis-isomer content as defined in claims 20,21 is not inventive over D3.

V.1.4. A composition comprising 85-90% of beta-carotene (approximately a 1:1 mixture of cis isomers and trans-isomers) is disclosed in D4 (see page 7, lines 19-25). This is clearly a cis-ismoer enriched composition. The compositions of D4 may be used for preventing the development of atherosclerosis and the resulting cardiovascular disease (e.g. coronary artery disease). Claims 1-16 and 22 are considered being not novel over D4.

V.1.5. Although the teaching of D5 (see col. 3, especially lines 29,30 and 52-55) is focussed on preparing carotenoid compositions with not too high cis-isomer concentrations, a clear indication is given to a skilled person how to increase the cis-isomer portion. Compositions with higher cis-isomer amount are therefore easy acchievable for a skilled person; the subject matter of claims 1-20 lack an inventive step. Regarding current claim 20, the cis-increasing temper-step as described in col. 3 of D5 modifies the isomer profile of the cis/trans system.

V.1.6. D6/D7 describe a process for extracting astaxanthin pigment from the blue-green algae, whereby a culture suspension is treated with microwaves to destroy the cell walls and microbodies, and drying the obtained material containing astaxanthin pigment. Nothing is said in D6/D7 about the influence of the cis/trans equilibrium caused by micro wave irradiation.

V.1.7. The applicant should be aware of the fact, that all cis-isomer enriched compositions or preparations are considered being novelty destroying for claim 1, independently from the process of making them. Products claimed by so-called 'products-by-process' claims have to be novel as such to be patentable.

VII. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D7 is not mentioned in the description, nor are these documents identified therein.